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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,656	06/20/2003	Bill E. Cham	13131-0310 (44378-282108)	8075
23370	7590	08/12/2004	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,656

Applicant(s)

CHAM ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claims 1 and 2, drawn to a modified immunodeficiency virus particle.
- Group II, claims 1 and 2, drawn to a modified hepatitis virus particle.
- Group III, claims 1 and 2, drawn to a modified pestivirus particle.
- Group IV, claims 3-5, 18, 19 and 22-27 drawn to a method of making a modified immunodeficiency virus particle.
- Group V, claims 3-5, 18, 19 and 22-27 drawn to a method of making a modified hepatitis virus particle.
- Group VI, claims 3-5, 18, 19 and 22-27 drawn to a method of making a modified pestivirus particle.
- Group VII, claims 6-8, drawn to an antigen delivery vehicle comprising patient specific antigens.
- Group VIII, claim 9, drawn to a method of providing protection against an infectious viral particle.
- Group IX, claim 10, drawn to a method of providing protection against a patient specific infectious viral particle.

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- Group X, claims 11-17 and 20-27, drawn to a method of provoking an immune response using patient specific antigens.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the asserted special technical feature linking all claims is a modified viral particle that has been partially delipidated. Oxford (U.S. Patent 5,698,432) teaches the production of inactivated (delipidated) whole HIV virus using β -propiolactone (claim 6 of Oxford). Since the asserted special technical feature is anticipated by the prior art, the claims lack unity of invention.

- a) Groups I-III are drawn to different viral particle compositions comprising immunodeficiency virus, hepatitis virus and pestivirus particles. A search for an immunodeficiency virus is not co-extensive for hepatitis and pestivirus. These viruses have different structures, genomic content, modes of operation, function and effect.
- b) Inventions (I-III) and (IV-VI) are related as process of making and product made, respectively. The inventions are distinct if either or both of the following can be shown:
(1) that the process as claimed can be used to make other and materially different product or
(2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products can be made by a materially different process, such as treatment with a detergent.
- c) Groups (I-III) and VII are drawn to different compositions. The compositions of Groups I-III contain viral particles. The composition of Group VII contains patient specific

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antigens. A search for the viral particles of Groups I-III is not co-extensive with a search for patient specific antigens.

- d) Inventions (I-III) and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a diagnostic assay.
- e) Inventions (I-III) and (IX-X) are unrelated. The products of Groups I-III are not required for the method of providing protection using patient-specific delipidated viral particles.
- f) Inventions IV, V, VI, VIII, IX and X are all unrelated. The methods of Groups IV-VI are drawn to the delipidation of different types of viral particles (immunodeficiency viruses, hepatitis viruses and pestiviruses). A search for delipidation of immunodeficiency viruses is not co-extensive with a search for delipidation of hepatitis viruses or pestiviruses. The method of Group VIII is drawn to providing protection against infectious viral particles. The methods of Groups IV-VI (collectively) and Group VIII do not share modes of operation, function or effect. They are not disclosed as capable of use together. The methods of Groups IX and X are drawn to providing protection using patient specific delipidated viral particles, not required for the practice of any other method or disclosed as capable of use with other methods.
- g) Inventions (IV-VI) and VII are unrelated. The methods of Groups IV-VI do not require the patient-specific antigen delivery vehicle of Group VII.

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- h) Inventions VII and VIII are unrelated. The method of providing protection against an infectious viral particle does not require the patient-specific antigen of Group VII.
 - i) Inventions VII and (IX-X) are related as product and process of use. The product of Group VII can be used in a diagnostic assay.
3. Because these inventions are distinct for the reasons given above and the literature search required for one group is not co-extensive for any other group, restriction for examination purposes as indicated is proper. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SBC

Stacy B. Chen
July 30, 2004

James C. Housel
8/7/04
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